

consideration. The objections and rejections set forth in the Office Action are addressed below in the order in which they are raised.

### Specification

The disclosure has been objected to as referring to a nucleic acid molecule comprising the cDNA encoding the full length hIL-1L1 protein deposited with the ATCC, but without specifying the actual ATCC Accession Number for the deposit and date in with the deposit was made. Applicants are in the process of facilitating the deposit of the hIL-1L1 clone with the ATCC and, upon receipt of an Accession Number and deposit date, will amend the specification accordingly.

### Claims

Claims 12, 14, 18 and 19 have been objected to because they recite non-elected SEQ ID No. 4. Accordingly these claims have been amended to delete reference to non-elected SEQ ID No. 4. Furthermore, claims 18 and 19 have been objected to because these claims recite Accession Nos. for EST sequences. Accordingly, Applicants are preparing an amended sequence listing so that said sequences are referred to by a sequence identifier instead of an Accession Number. The amended sequence listing will be submitted in a supplementary response when it becomes available.

## **REJECTIONS**

### Rejections Under 35 U.S.C. §112, first paragraph-Enablement

The Office Action states that claims 17 and 19 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains...to make and/or use the invention.” In particular, the Office Action states that the referenced ATCC deposits require either a specific ATCC deposit number designation or a corresponding assurance of record that such a deposit, to be made publicly-available upon issue of a patent, will be made. Applicants are currently in the process of preparing the corresponding DNA clones for deposit with the ATCC. Accordingly, Applicants’ attorney of record hereby provides assurances that, during the

pendency of the application, access to the invention will be afforded to the Commissioner upon request, that all restrictions upon availability to the public will be irrevocably removed upon granting of the patent, that the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or the enforceable life of the patent, whichever is longer, that a test of the viability of the biological material at the time of the deposit will be made, and that the deposit will be replaced if it should ever become inviable. The specific ATCC deposit numbers and corresponding amendments to the specification and claims will be made when said deposit numbers become available.

The Office Action further states that claims 12, 14-17, 20, 21 and 24 have been rejected under 35 U.S.C. § 112, first paragraph, because “the specification, while being enabling for an isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID No. 1, does not reasonably provide enablement for an isolated nucleic acid with is at least 70-90% identical to the nucleotide sequence set forth in SEQ No. 1...”. Solely in order to expedite prosecution of the application and not in acquiescence to the Examiner’s rejection, Applicants have amended subject claims 12, 18, 20 and 21 referring to isolated nucleic acids at least “70-90% identical” so that the structural limitation “hybridizes under stringent conditions” to a referenced DNA sequence is included in the claim. Applicants note that pending claims 14-17 and 19 are already so restricted to hybridizing structures. Applicants expressly reserve the right to pursue without prejudice the originally filed claims as well as other disclosed subject matter at a latter date. Applicants note that such “hybridization” language is provided in exemplary biotechnology claims for which the written description requirement is deemed met in the U.S.P.T.O.’s Revised Interim Written Description Guidelines Training Material (see e.g. Example 9). Accordingly, Applicants respectfully assert that the instant claim amendments obviate this grounds for rejection and reconsideration and withdrawal of the rejection is respectfully requested.

#### Rejections Under 35 U.S.C. §112, first paragraph- Written Description

The Office Action further states that claims 12, 14-17, 20, 21 and 24 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In

particular, the Office Action refers to the previously-cited sole reliance on percent identity language in the subject claims to describe the claimed genus of IL-1L1 sequences. Solely in an effort to expedite prosecution of the application, and not in acquiescence to this rejection, Applicants have amended the subject claims as indicated above in Applicants' response to the enablement rejection. Applicants expressly reserve the right to pursue without prejudice the originally filed claims as well as other disclosed subject matter at a latter date. Accordingly, Applicants believe the instant rejection is thereby obviated and reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph- Definiteness

The Office Action further states that claims 14 and 19 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claims the subject matter which applicant regards as the invention. In particular, the Office Action states that claims 14 and 19 have been rejected "as vague and indefinite because the claim...recites "An isolated nucleic acid sequence which hybridizes to," which, the Office Action states "is a conditional term and renders the claims indefinite." Solely in an effort to expedite prosecution, and not in acquiescence to the instant rejection, Applicants have amended subject claims 12, 14, 18, 19, 20 and 21 to include the specific hybridization condition "0.2 x SSC at 50° C" (supported, e.g. at page 35, line 14). Applicants expressly reserve the right to pursue without prejudice the originally filed claims as well as other disclosed subject matter at a latter date. Accordingly, Applicants believe these amendments obviate the instant rejection under 23 U.S.C. § 112, second paragraph, and reconsideration and withdrawal of the rejection is respectfully requested.

The Office Action further states that claim 17 and 19 are vague and indefinite for the recital of "XXXXXX" as a deposit number. For the reasons indicated above, Applicants respectfully request reconsideration and withdrawal of the rejection upon their submission of appropriate ATCC deposit numbers, when they become available.

### Rejections Under 35 U.S.C. §102, first paragraph-Enablement

The Office Action states that claims 12, 14-16, 18-19, 20-21 and 24 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ford et al. (U.S. Patent No. 6,294,655). In particular, the Office Action states that “one of the polynucleotides disclosed by Ford et al. shares 97.1% sequence similarity to the instantly claimed polynucleotides of SEQ ID no. 1, and another shares 86.6%....etc.” Specific alignments of the subject sequences to the claimed sequences have been kindly provided by the Examiner. Relevant to consideration of this rejection, Applicants have also provided additional references to the Examiner in a supplementary IDS (filed on July 17, 2001) which was based upon the International Search Report in the corresponding PCT application. Applicants respectfully traverse the instant rejection and request clarification of the rejection for the reasons that follow.

Applicants note that Ford et al. is based upon an application that was filed on October 13, 1999. Applicants’ priority application was filed on July 16, 1999 (USSN 60/144,298). First, it is unclear how the cited Ford patent could anticipate the instant claimed invention under 35 U.S.C. § 102**b**, because the Ford patent was not presumptively “described in a printed publication” until it issued at U.S. Patent on September 25, 2001 - which is not “more than one year prior to the date of the application for patent in the United States” of the instant invention. Furthermore, although the Ford et al. application claims priority to an earlier filed application (i.e. USSN09/348,942 filed on July 7, 1999), it is a continuation-in-part of this earlier-filed application and, accordingly, it is not clear from the face of the reference that the cited patent reference is entitled to an earlier date of priority than Applicants’ priority filing. Applicants respectfully request clarification of the asserted date of priority of the Ford patent. Notwithstanding this request for clarification, Applicants are prepared to file a Declaration under 37 CFR 1.131 attesting to their earlier date of invention and/or diligence in reducing to practice the subject invention, once said relevant date of priority is established. Accordingly, Applicants will supply the stated Declaration, if necessary, upon clarification of the asserted date of priority from the Examiner.

## CONCLUSION

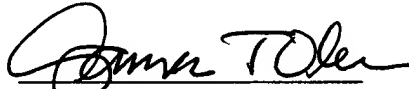
For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal and/or clarification of the pending rejections. Applicants believe that certain claims now pending are in condition for allowance, and notification of such is respectfully requested. If for any reason a telephonic conference with the Applicant would be helpful in expediting prosecution of the instant application, the Examiner is invited to call Applicants' Attorney at (617) 832-1764.

If there are any other fees due in connection with the filing of this Response, please charge the fees to our Deposit Account No. 06-1448.

Respectfully submitted,  
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12. **(Amended)** An isolated nucleic acid comprising a nucleotide sequence which is at least 70% identical to the entire nucleotide sequence set forth in SEQ ID No. 1 [or 4] or complement thereof, wherein said isolated nucleic acid hybridizes under stringent conditions of 0.2 x SSC at 50° C to SEQ ID No.1.

14. **(Amended)** An isolated nucleic acid sequence which hybridizes under stringent conditions of 0.2 x SSC at 50° C to a nucleic acid selected from the group consisting of: the nucleic acid sequence corresponding to nucleotide 310 to 2562 of SEQ ID No. 1, the nucleic acid sequence corresponding to nucleotide 1 to 29 of SEQ ID No. 1, SEQ ID No. 2, and SEQ ID No. 3[, and the nucleic acid sequence corresponding to nucleotide 390 to 1284 of SEQ ID No. 4].

17. **(Amended)** The isolated nucleic acid of claim 14, which is comprised of a nucleic acid fragment corresponding to an IL-1L1 gene insert of a vector having ATCC Deposit No. XXXXXX [or XXXXXX].

18. **(Amended)** An isolated nucleic acid comprising at least 100 consecutive nucleotides having a nucleotide sequence which is at least 75% identical to a nucleotide sequence set forth in SEQ ID No. 1, [or 4] or a complement thereof, with the proviso that the nucleic acid is not selected from the group consisting of the EST sequences having GenBank Accession Nos. AI040890, AI469873, AA722902, AI167887, R70041, R70089, W08205, AI391145, W20594, AI684888, wherein said isolated nucleic acid hybridizes under stringent conditions of 0.2 x SSC at 50° C to SEQ ID No.1.

19. **(Amended)** An isolated nucleic acid comprising at least about 100 consecutive nucleotides, which nucleic acid hybridizes under stringent conditions of 0.2 x SSC at 50° C to a nucleotide sequence set forth in SEQ ID No[s:]: 1, [or 4] or a complement thereof or to the nucleic acid having ATCC Designation No. XXXXXX [or XXXXXX], provided that the nucleic acid is not a member selected from the group consisting of the EST sequences having GenBank Accession Nos. AI040890, AI469873, AA722902, AI167887, R70041, R70089, W08205, AI391145, W20594, AI684888.

20. **(Amended)** An isolated nucleic acid comprising a nucleotide sequence which is at least about 75% identical to the entire nucleotide sequence set forth in SEQ ID No. 2, wherein said isolated nucleic acid hybridizes under stringent conditions of 0.2 x SSC at 50° C to SEQ ID No.2.

21. **(Amended)** An isolated nucleic acid comprising a nucleotide sequence which is at least about 90% identical to the entire nucleotide sequence set forth in SEQ ID No. 3, wherein said isolated nucleic acid hybridizes under stringent conditions of 0.2 x SSC at 50° C to SEQ ID No.3.

24. **(Amended)** The isolated nucleic acid of any of claims 12, 14, 18, 19, 20, or 21 [or 22] further comprising a label.

25. **(New)** An isolated nucleic acid encoding a polypeptide sequence of SEQ ID No. 10.

Marked-Up Version of the Specification Showing Changes with Amendments for U.S.S.N.  
09/617,720

On page 1, line 2, immediately after the title "The *IL-1L1* Gene and Polypeptide Procuts," please insert the following paragraph:

--Related U.S. Applications

This application claims the benefit of U.S. Provisional Application No. 60/144,298, filed July 16, 1999, which application is hereby incorporated by reference. --